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Abbreviated 510(k) Notification

510(k): ELI 150 Electrocardiograph Device Summary

JUN 18 2010

Submitter: **Date:** May 25, 2010

Charles Morreale, Regulatory Affairs Manager
Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224
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Contact: Charles Morreale (see above)

Trade Name: ELI 150 Electrocardiograph

Common Name: Electrocardiograph
Classification Name: Electrocardiograph
(Per 21 CFR 870.2340)

Legally marketed devices to which S. E. is claimed

The Mortara Instrument's ELI 150 Electrocardiograph is the next generation and is substantially equivalent to the legally marketed predicate device:

- ELI 100 by Mortara Instrument (K920627)
- ELI 350 by Mortara Instrument (K082946)

The proposed ELI 150 is a modification of the Mortara predicate device. It will include the addition of Pediatric Criteria for the VERITAS™ Interpretive Algorithm with the current technology resulting in the next generation Mortara ELI 150 Electrocardiograph.

Description:

The ELI 150 is multi-channel, resting interpretation electrocardiographs. The ELI 150 simultaneously acquires data from up to 12 leads. Once the data is acquired, it can be reviewed, and/or stored, and/or printed.

The electrocardiogram (ECG) is a graphic description of the electrical activity of the heart. This activity is recorded from the body surface by a group of electrodes positioned at predefined places to reflect the activity from different perspectives. The cardiac data acquired and provided by the ELI 150 is used by trained medical personnel to assist in the diagnosis of symptomatic patients with various rhythm patterns.

The ELI 150 is designed to be installed on a transport cart. The ELI 150 is able to acquire, analyze, display and print electrocardiograms acquired through its internal Mortara front-end amplifier. The size of the screen will allow preview of the record for the technician to assess the quality of the acquired ECG.

The ELI 150 utilizes a monochrome (or optional color) LCD for display of ECG waveforms, menu options and status information. A custom keyboard is part of the ELI 150 design and allows patient data entry as well as control of the functions and options available for the unit. The ELI 150 custom keyboard will include alphabetic, numeric, symbol, cursor control and special function keys. The ELI 150 incorporates a thermal writer that allows printouts using several formats available to the user, from the standard to the Cabrera formats. The writer is also used by the unit for real time, continuous rhythm printout.

The ELI 150 will offer storage capability in order to retrieve or transmit stored records. Transmission can be achieved using one of the optional communication media designed in the unit: RS 232, LAN, WLAN, Modem, and / or GSM/GPRS module.

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Intended Use:

The ELI 150 is intended to be a high-performance, 12-lead, multifunctional electrocardiograph. As a resting electrocardiograph, ELI 150 simultaneously acquires data from 12 leads. Once the data is acquired, it can be reviewed and/or stored, and/or printed. It will be a device primarily intended for use in hospitals, but may be used in medical clinics and offices of any size.

Indications for Use:

- The device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use on adult and pediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.

Summary discussion:

The ELI 150 modification includes the addition of pediatric criteria to the VERITAS Interpretive Algorithm that was previously cleared through 510(k) Premarket Notification (K082946). Clinical ECG's were randomly collected from various pediatric cardiology centers. These ECG's were then submitted to a cardiologist for reading without automatic interpretation (blind reading) and in a standard 3x5 format at 10 mm/mV and 25 mm/s. The same ECGs were also interpreted by the VERITAS Pediatric ECG Interpretation algorithm.

This data was utilized to calculate the Sensitivity, Specificity, Positive Predictive Accuracy and Negative Predictive Accuracy for the algorithm. This information is provided within the *Physician's Guide to VERITAS with Adult and Pediatric Resting ECG Interpretation.*

ELI 150 utilizes the same VERITAS Interpretive Algorithm as the predicate device. The main subject of this 510(k) submission is the evolution of the ELI 150 through a software modification to incorporate the Mortara VERITAS Interpretive Algorithm with pediatric criteria. Therefore, the modified device performs as safety and effectively as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Mortara Instrument, Inc.
c/o Charles Morreale
Regulatory Affairs Manager
7865 North 86th Street
Milwaukee, WI 53224

Re: K101115
Trade/Device Name: ELI 150 Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiographs
Regulatory Class: Class II (two)
Product Code: DPS
Dated: April 16, 2010
Received: April 21, 2010

Dear Mr. Morreale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101115

Device Name: Mortara ELI 150 Electrocardiograph

Indications for Use:

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- The device is not intended to be used as a vital signs physiological monitor.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101115